AMENDED IN ASSEMBLY AUGUST 7, 2000 AMENDED IN ASSEMBLY JUNE 20, 2000 AMENDED IN SENATE MAY 3, 2000 AMENDED IN SENATE MARCH 23, 2000

SENATE BILL

No. 1596

Introduced by Senator Ortiz (Principal coauthor: Senator Alpert)

February 18, 2000

An act to amend Sections 100330, 103850, and 103885 of the Health and Safety Code, relating to health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1596, as amended, Ortiz. Health reporting: confidentiality of information.

Existing law provides for the confidentiality of certain records and other information procured by the State Department of Health Services in connection with morbidity and mortality studies, the Birth Defects Monitoring Program, and the statewide cancer reporting system. Existing law requires an authorized disclosure of this information to be made pursuant to an agreement that the information will be kept confidential.

This bill would revise and recast these provisions to expand the types of records to which these provisions apply to include medical and pathology records and records of health status, and to require that this information be used solely for statistical, scientific, and medical research purposes relating SB 1596 -2-

to the cause of condition of health, except as specified, in accordance with prescribed procedures. The bill would require the confidentiality agreement to be in writing. It would also provide that any person who violates these provisions would be subject to civil and criminal penalties and actions. and that further access to confidential information maintained by the department may be denied. creating new crimes, this bill would impose a state-mandated local program.

This bill would incorporate additional changes in Section 103885 of the Health and Safety Code, proposed by AB 48, to be operative only if AB 48 and this bill are both chaptered and become effective January 1, 2001, and this bill is chaptered last.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 100330 of the Health and Safety 2 Code is amended to read:
- 3 100330. (a) All data including, but not limited to,
- 4 medical and pathology records, records of health status,
- 5 records of interviews, questionnaires, written reports,
- 6 statements, notes, and memoranda procured by the 7 department or by any other person, agency, or
- 8 organization acting jointly with the department,
- 9 including public or private colleges and universities, in
- 10 connection with morbidity and mortality studies and
- 11 research investigations to determine any cause of
- 12 condition of health shall be confidential and shall be used
- 13 solely for statistical, scientific, and medical research
- 14 purposes relating to the cause or condition of health,
- 15 except as otherwise provided in this section.

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(b) Before the department discloses confidential data to any other person, agency, or organization acting jointly with the department, the requesting entity to the department that the entity demonstrate has established procedures and the ability to maintain the confidentiality of the information.

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- (c) All confidential data may be used department when necessary for the purpose controlling nuisances dangerous to the public health 10 including, but not limited to, communicable, contagious, and infectious diseases.
- (d) Confidential data may be disclosed by 13 department to other local, state, or federal public health 14 or environmental agencies, or to collaborating medical confidential the 15 researchers. when information 16 necessary to carry out the duties of the agency or researcher in the investigation, control, or surveillance of disease, as determined by the department.
- (e) Any disclosure authorized by this section shall 20 include only the information necessary for the stated purpose of the requested disclosure, and shall be made 22 only upon written agreement that the information will be kept confidential and will not be further disclosed without written authorization of the department.
 - confidential (f) The furnishing of data to the department or its authorized representative or to any other cooperating individual, agency, or organization in any study in accordance with this section shall not expose any person, agency, or entity furnishing data to liability and shall not be considered to be the violation of any privileged or confidential relationship.
- (g) No part of the confidential data shall be available 33 for subpoena nor shall it be disclosed, discoverable, or compelled to be produced in any civil, administrative, or other proceeding, nor shall these data 36 be deemed admissible as evidence in any civil, criminal, administrative, or other tribunal or court for any reason.
- 38 (h) (1) Notwithstanding any other provision of law, any person who violates this section shall be subject to

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civil and criminal penalties and other actions in accordance with Section 56.36 of the Civil Code.

- who intentionally (2) Any person discloses confidential data to any third party, except as authorized in this section, may be denied further access to confidential data maintained by the department.
- prohibit (i) Nothing in this section shall publication by the department of reports and statistical compilations relating to morbidity and mortality studies 10 that do not identify individual cases and sources of information or religious affiliations.
- 12 SEC. 2. Section 103850 of the Health and Safety Code 13 is amended to read:
- 103850. (a) All information collected pursuant to this 15 chapter shall be confidential and shall be used solely for the purposes provided in this chapter. Access to the information shall be limited to the department, authorized program staff, and persons with a valid scientific interest, who meet qualifications as determined by the director, who are engaged in demographic, epidemiological, or other similar studies related to health, and who agree, in writing, to maintain confidentiality, except as otherwise provided in this section.
- (b) Confidential information may be disclosed 25 other local. state, or federal public health or agencies, environmental or to collaborating medical confidential information researchers, when the necessary to carry out the purposes of this chapter.
- (c) The department shall maintain an accurate record 30 of all persons who are given access to the information in the system. The record shall include: the name of the person authorizing access; name, title, and organizational affiliation of persons given access; dates of access; and the specific purpose for which information is to be used. The record of access shall be open to public inspection during 36 normal operating hours of the state department.
 - (d) All research proposed to be conducted by persons, agencies, or organizations other than the department and program staff, using the information in the system, shall first be reviewed and approved by the director and the

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State Committee for the Protection of Human Subjects. Satisfaction of the terms of the director's rules for data 3 access shall be deemed to establish a valid scientific 4 interest for purposes of subdivision (a), entitling the 5 researcher to review records collected pursuant to 6 Section 103830 and to contact case subjects and controls. Before confidential information is disclosed to any other person, agency, or organization, the requesting entity shall demonstrate to the department that the entity has 10 established the procedures and ability to maintain the confidentiality of the information.

(e) Any disclosure authorized by this section shall 13 include only the information necessary for the stated 14 purpose of the requested disclosure, and shall be made 15 only upon written agreement that the information will be 16 kept confidential and will not be further disclosed without written authorization of the department.

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- (f) The furnishing of confidential information to the 19 department or its authorized representative or to any 20 other cooperating individual, agency, or organization in any study in accordance with this section shall not expose any person, agency, or entity furnishing information to liability and shall not be considered to be the violation of any privileged or confidential relationship.
- (g) Whenever department, pursuing the program 26 objectives, deems it necessary to contact case subjects and department shall submit a protocol 27 controls, the 28 describing the research to the director and to the State 29 Committee for the Protection of Human Subjects. Once 30 a approved by that committee, protocol is department shall be deemed to have established a bona fide research purpose, and shall be entitled to complete approved project and contact case subjects and 34 controls without securing any additional approvals or waivers from any entity.
- (h) No part of the confidential information shall be 37 available for subpoena nor shall it be disclosed, 38 discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding, nor shall this information be deemed admissible as evidence in any

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civil, criminal, administrative, or other tribunal or court for any reason.

- (i) Nothing in this section shall prohibit the publication by the department of reports and statistical compilations relating to birth defects, stillbirth, miscarriage that do not in any way identify individual cases or individual sources of information.
- (j) (1) Notwithstanding any other provision of law, any person who violates this section shall be subject to 10 civil and criminal penalties and other actions accordance with Section 56.36 of the Civil Code.
- (2) Any person who discloses confidential data, in agreement 13 violation of a written maintain 14 confidentiality, to any third party, except as authorized in this section, may be denied further access to confidential 16 data maintained by the department.
- SEC. 3. Section 103885 of the Health and Safety Code 18 is amended to read:
- 103885. (a) The director shall establish a statewide 20 system for the collection of information determining the 21 incidence cancer. using population-based of 22 registries modeled after the Cancer Surveillance 23 Program of Orange County. As of the effective date of this 24 section, the director shall begin phasing in the statewide 25 cancer reporting system. By July 1, 1988, all county or 26 regional registries shall be implemented or initiated. By July 1, 1990, the statewide cancer reporting system shall be fully operational. Within 60 days of the effective date director section. the shall implementation and funding schedule to the Legislature. 30
- (b) The department may designate any demographic 32 parts of the state as regional cancer incidence reporting areas and may establish regional cancer registries, with 34 the responsibility and authority to carry out the intent of 35 this section in designated areas. Designated regional 36 registries shall provide, on a timely basis, cancer incidence data as designated by the state department to 38 the department. The department may contract with an agency, including, but not limited to, a health systems agency, single county health department, multicounty

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health department grouping, or nonprofit professional association, representing a designated cancer reporting 3 region for the purposes of collecting and collating cancer 4 incidence data.

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- (c) The director shall designate cancer as a disease 6 required to be reported in the state or any demographic parts of the state in which cancer information is collected under this section. All cancers diagnosed or treated in the reporting area shall thereafter be reported 10 representative of the department authorized to compile cancer data, or any individual, agency, designated with organization to cooperate that representative.
- (d) (1) Any hospital or other facility providing 15 therapy to cancer patients within an area designated as 16 a cancer reporting area shall report each case of cancer to the department or the authorized representative of the department in a format prescribed by the department. If the hospital or other facility fails to report in a format 20 prescribed by the department, the department's 21 authorized representative may access the information 22 from the hospital or the facility and report it in the appropriate format. In these cases, the hospital or other health facility shall reimburse the state department or the 25 authorized representative for its cost to access and report 26 the information.
- (2) Any physician and surgeon, dentist, podiatrist, or 28 other health care practitioner diagnosing or providing 29 treatment for cancer patients shall report each cancer 30 case to the department or the authorized representative 31 of the department except for those cases directly referred 32 to a treatment facility or those previously admitted to a treatment facility for diagnosis or treatment of that 34 instance of cancer.
- (e) Any hospital or other facility that is required to 36 reimburse the department or its authorized representative for the cost to access and report the 38 information pursuant to subdivision (d) shall provide to the department or its 40 representative within 60 days of the date this payment is

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demanded. In the event any hospital or other facility fails to make the payment to the department or its authorized representative within 60 days of the date the payment is department demanded. the or its authorized 5 representative may, at its discretion, assess a late fee not to exceed $1^{1/2}$ percent per month of the outstanding balance. Further, in the event that the department or its authorized representative takes a legal action to recover its costs and any associated fees, and the department or 10 its authorized representative receives a judgment in its favor, the hospital or other facility shall also reimburse the authorized representative for 12 department or its 13 additional costs it incurred to pursue the legal action. 14 Late fees and payments made to the department by 15 hospitals or other facilities pursuant to this subdivision 16 shall be considered as reimbursements of the additional 17 costs incurred by the department. 18

- (f) All physicians and surgeons, hospitals, outpatient 19 clinics, nursing homes and all other facilities, individuals or agencies providing diagnostic or treatment services to patients with cancer shall grant to the department or the 22 authorized representative access to all records that would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or medical status 25 of any identified cancer patient. Willful failure to grant access to those records shall be punishable by a fine of up to five hundred dollars (\$500) each day access is refused. Any fines collected pursuant to this subdivision shall be deposited in the General Fund.
- (g) (1) All data including, but not limited to, medical pathology records, records of health status, reports, questionnaires. interviews. statements. notes. and memoranda collected pursuant to this section shall be confidential. Access shall be limited to the department and any regional registry designated by the department except as otherwise provided in this subdivision. 36
 - (2) The department and any regional cancer registry designated by the department may enter agreements to furnish confidential data to other states' cancer registries, federal cancer control agencies, local

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health officers, or health researchers for the purposes of determining the sources of malignant neoplasms and evaluating measures designed to eliminate, alleviate, or ameliorate their effect. Before confidential 5 out-of-state disclosed to those registries, officers, or researchers, the requesting entity shall agree maintain the confidentiality writing to information, and, in the case of researchers, shall do both of the following:

(A) Obtain approval of their committee for protection of human subjects established in accordance with Part 46 (commencing with Section 46.101) of Title 12 45 of the Code of Federal Regulations.

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- (B) Provide documentation to the department that 15 demonstrates to the department's satisfaction that the 16 entity has established the procedures and ability to maintain the confidentiality of the information.
- (3) Confidential data may be disclosed to other local, 19 state, or federal public health or environmental agencies, collaborating medical researchers, confidential data are necessary to carry out the duties of the agency or researcher in the investigation, control, or surveillance of disease, as determined by the department.
- (4) Any disclosure authorized by this section shall 25 include only the information necessary for the stated purpose of the requested disclosure and shall be made only upon written agreement that the information will be kept confidential and will not be further disclosed without written authorization of the department.
- (5) The furnishing confidential data of the 31 department or its authorized representative or to other cooperating individual, agency, or organization in any study in accordance with this subdivision shall not 34 expose any person, agency, or entity furnishing data to liability and shall not be considered to be the violation of 36 any privileged or confidential relationship.
- (6) No part of the confidential data shall be available 38 for subpoena nor shall it be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding, nor shall these data

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be deemed admissible as evidence in any civil, criminal, administrative, or other tribunal or court for any reason.

- (7) (A) Notwithstanding any other provision of law, any person who violates this subdivision shall be subject to civil and criminal penalties and other actions in accordance with Section 56.36 of the Civil Code.
- intentionally (B) Any person who confidential data to any third party, except as authorized in this subdivision, may be denied further access to 10 confidential data maintained by the department.
- prohibit the (8) Nothing in this subdivision shall 12 publication by the department of reports and statistical of 13 compilations relating to the causes malignant 14 neoplasms or measures to eliminate, alleviate. 15 ameliorate the effect of malignant neoplasms that do not 16 identify individual cases and sources of information or religious affiliations.
- (h) For the purpose of this section, "cancer" means all 19 malignant neoplasms, regardless of the tissue of origin, 20 including malignant lymphoma, Hodgkins disease, and 21 leukemia, but excluding basal cell and squamous cell 22 carcinoma of the skin.
- (i) Nothing in this section shall preempt the authority 24 of facilities or individuals, providing diagnostic treatment services to patients with cancer, to maintain their own facility-based tumor registries.
 - (j) It is the intent of the Legislature that department, in establishing a system pursuant to section, maximize the use of available federal funds.
 - SEC. 4. Section 103885 of the Health and Safety Code is amended to read:
- 103885. (a) The director shall establish a statewide system for the collection of information determining the using population-based 34 incidence of cancer, 35 cancer registries modeled after the Cancer Surveillance 36 Program of Orange County. As of the effective date of this section, the director shall begin phasing in the statewide 38 cancer reporting system. By July 1, 1988, all county or regional registries shall be implemented or initiated. By July 1, 1990, the statewide cancer reporting system shall

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be fully operational. Within 60 days of the effective date this section, the director shall submit implementation and funding schedule to the Legislature.

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- (b) The department may designate any demographic 5 parts of the state as regional cancer incidence reporting areas and may establish regional cancer registries, with the responsibility and authority to carry out the intent of this section in designated areas. Designated regional registries shall provide, on a timely basis, cancer 10 incidence data as designated by the state department to the department. The department may contract with an agency, including, but not limited to, a health systems agency, single county health department, multicounty 14 health department grouping, or nonprofit professional association, representing a designated cancer reporting 16 region for the purposes of collecting and collating cancer incidence data.
- (c) The director shall designate cancer as a disease 19 required to be reported in the state or any demographic 20 parts of the state in which cancer information is collected 21 under this section. All cancers diagnosed or treated in the reporting area shall thereafter be reported representative of the department authorized to compile the cancer data, or any individual, agency, organization designated to cooperate with that representative.
- (d) (1) Any hospital or other facility providing 28 therapy to cancer patients within an area designated as a cancer reporting area shall report each case of cancer to the department or the authorized representative of the department in a format prescribed by the department. If the hospital or other facility fails to report in a format prescribed by the department, the department's 34 authorized representative may access the information 35 from the hospital or the facility and report it in the 36 appropriate format. In these cases, the hospital or other health facility shall reimburse the state department or the authorized representative for its cost to access and report the information.

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- (2) Any physician and surgeon, dentist, podiatrist, or 2 other health care practitioner diagnosing or providing treatment for cancer patients shall report each cancer case to the department or the authorized representative of the department except for those cases directly referred 6 to a treatment facility or those previously admitted to a treatment facility for diagnosis or treatment of that instance of cancer.
- (e) Any hospital or other facility that is required to department 10 reimburse the or its authorized representative for the cost to access and report the 12 information pursuant to subdivision (d) shall provide 13 payment to the department or its authorized 14 representative within 60 days of the date this payment is 15 demanded. In the event any hospital or other facility fails 16 to make the payment to the department or its authorized representative within 60 days of the date the payment is 17 department 18 demanded. or its 19 representative may, at its discretion, assess a late fee not 20 to exceed $1^{1/2}$ percent per month of the outstanding 21 balance. Further, in the event that the department or its 22 authorized representative takes a legal action to recover 23 its costs and any associated fees, and the department or 24 its authorized representative receives a judgment in its 25 favor, the hospital or other facility shall also reimburse the 26 department or its authorized representative for any additional costs it incurred to pursue the legal action. 28 Late fees and payments made to the department by 29 hospitals or other facilities pursuant to this subdivision 30 shall be considered as reimbursements of the additional 31 costs incurred by the department.
- (f) All physicians and surgeon surgeons, hospitals, 33 outpatient clinics, nursing homes and all other facilities, 34 individuals or agencies providing diagnostic or treatment 35 services to patients with cancer shall grant to the 36 department or the authorized representative access to all 37 records that would identify cases of cancer or would 38 establish characteristics of the cancer, treatment of the cancer, or medical status of any identified cancer patient. 40 Willful failure to grant access to those records shall be

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punishable by a fine of up to five hundred dollars (\$500) each day access is refused. Any fines collected pursuant to this subdivision shall be deposited in the General Fund.

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- (g) All information reported (1) All data including, 5 but not limited to, medical and pathology records, interviews, records of health status, questionnaires, notes, and memoranda collected reports. statements. pursuant to this section shall be confidential as provided in Section 100330, except that confidential. Access shall 10 be limited to the department and any regional -cancer registry designated by the department shall use the information to determine except as otherwise provided in this subdivision—the sources of malignant neoplasms 14 and evaluate measures designed to eliminate, alleviate, or ameliorate their effect.
- (2) The department and any regional cancer registry department designated by the may enter 18 agreements to furnish confidential information data to other states' cancer registries, federal cancer control agencies, local health officers, or health researchers for 21 the purposes set forth in this subdivision if of determining 22 the sources of malignant neoplasms and evaluating 23 measures designed to eliminate, alleviate, or ameliorate 24 their effect. Before confidential data are disclosed to 25 those out-of-state registries, agencies, officers. 26 researchers, the requesting entity shall agree in writing to maintain the confidentiality of the information, and, in the case of researchers, if they have obtained the shall do both of the following:
 - (A) Obtain approval of their committee protection of human subjects established in accordance with Part 46 (commencing with Section 46.101) of Title 45 of the Code of Federal Regulations.
- 34 (B) Provide documentation to the department 35 demonstrates to the department's satisfaction that the 36 entity has established the procedures and ability to maintain the confidentiality of the information. 37
- (3) Confidential data may be disclosed to other local, 38 state, or federal public health or environmental agencies, or to collaborating medical researchers, when

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confidential data are necessary to carry out the duties of the agency or researcher in the investigation, control, or surveillance of disease, as determined by the department.

- (4) Any disclosure authorized by this section shall 5 include only the information necessary for the stated purpose of the requested disclosure and shall be made only upon written agreement that the information will be kept confidential and will not be further disclosed without written authorization of the department.
- of confidential (5) The furnishing data department or its authorized representative or to any other cooperating individual, agency, or organization in any study in accordance with this subdivision shall not 14 expose any person, agency, or entity furnishing data to 15 liability and shall not be considered to be the violation of 16 any privileged or confidential relationship.
- (6) No part of the confidential data shall be available 18 for subpoena nor shall it be disclosed, discoverable, or compelled to be produced in any civil, 20 administrative, or other proceeding, not shall these data 21 be deemed admissible as evidence in any civil, criminal, administrative, or other tribunal or court for any reason.
- (7) (A) Notwithstanding any other provision of law, 24 any person who violates this subdivision shall be subject to civil and criminal penalties and other actions in accordance with Section 56.36 of the Civil Code.
- person who intentionally (B) Any discloses 28 confidential data to any third party, except as authorized in this subdivision, may be denied further access to confidential data maintained by the department.
- (8) Nothing in this subdivision shall prohibit the 32 publication by the department of reports and statistical compilations relating to the causes of malignant 34 neoplasms or measures eliminate, alleviate, to 35 ameliorate the effect of malignant neoplasms that do not 36 identify individual cases and sources of information or religious affiliations.
- (h) For the purpose of this section, "cancer" means all 38 either of the following:

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(1) All malignant neoplasms, regardless of the tissue of origin, including malignant lymphoma, Hodgkins disease, and leukemia, but excluding basal cell and squamous cell carcinoma of the skin.

(2) All primary intracranial and central nervous 6 system (CNS) tumors occurring in the following sites, irrespective of histologic type: brain, meninges, spinal cord, caudae equina, cranial nerves and other parts of the CNS, pituitary gland, pineal gland, and craniopharyngeal 10 duct.

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- (i) Nothing in this section shall preempt the authority of facilities or individuals, providing diagnostic treatment services to patients with cancer, to maintain 14 their own facility-based tumor cancer registries.
- (j) It is the intent of the Legislature that 16 department, in establishing a system pursuant to this section, maximize the use of available federal funds.
- 5. Section 4 of this billincorporates 19 amendments to Section 103885 of the Health and Safety 20 Code proposed by both this bill and AB 48. It shall only 21 become operative if (1) both bills are enacted and 22 become effective on or before January 1, 2001, (2) each 23 bill amends Section 103885 of the Health and Safety Code, 24 and (3) this bill is enacted after AB 48, in which case 25 Section 3 of this bill shall not become operative.
- SEC. 6. No reimbursement is required by this act 26 27 pursuant to Section 6 of Article XIII B of the California 28 Constitution because the only costs that may be incurred 29 by a local agency or school district will be incurred 30 because this act creates a new crime or infraction, 31 eliminates a crime or infraction, or changes the penalty 32 for a crime or infraction, within the meaning of Section 33 17556 of the Government Code, or changes the definition 34 of a crime within the meaning of Section 6 of Article 35 XIII B of the California Constitution.